1023

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Attorney Docket No.: 021044-007310US

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TOWNSEND and TOWNSEND and CREW LLP

BY: MARK T. DAVIS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

₹

WONG et al.

Application No.: 10/039,761

Filed: October 19, 2001

For: MODULATORS OF LEUKOCYTE ACTIVATION, COMPOSITIONS AND

METHODS OF USE

Examiner: Not Yet Assigned

Art Unit: 1623

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and

§1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Also enclosed is a copy of the Search/Examination report corresponding to the PCT application.

Application No.: 10/039,761

Page 2

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

PATENT

Annette S. Parent Reg. No. 42,058

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8th Floor San Francisco, California 94111-3834

Tel: 415-576-0200 Fax: 415-576-0300

MTD:mtd SF 1469342 v1 JUN 2 5 2003

PTO/SB/08B (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

2003 2003

ork Reduction Act of 😢 5, no persons are required to respond to a collection of information unless it contains a valid OMB contrologumber

Substitute for form 1449/P

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as n	nany sneets	s as necessary)	
 1		T	-

	Complete if Known	ME
Application Number	10/039,761	
Filing Date	October 19, 2001	JUN
First Named Inventor	Wong et al.	7, 36
Art Unit	1623	CEAL
Examiner Name	Not Yet Assigned	WER 1
Attorney Docket Number	021044-007310US	

	U.S. PATENT DOCUMENTS					
	Document Number					
Examiner	Cite No.1	Number Kind Code ² (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	AA	US-5,391,490	02-21-1995	Varshavsky et al.		
	AB	US-5,494,818	02-27-1996	Baker et al.		

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²			
	AC	Baek et al., "Molecular Cloning of a Novel Ubiquitin-specific Protease, UBP41, with Isopeptidase Activity in Chick Skeletal Muscle", The Journal of Biological Chemistry 272:41: 25560-25565 (1997).				
	AD	Gong et al., "Differential Regulation of Sentrinized Proteins by a Novel Sentrin-specific Protease", <i>The Journal of Biological Chemistry</i> 275:5: 3355-3359 (2000).				
	AE	Gong et al., "Identification of a Novel Isopeptidase with Dual Specificity for Ubiquitin- and NEDD8-conjugated Proteins", <i>The Journal of Biological Chemistry</i> 275:19: 14212-14216 (2000).				

Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: ROBIN M. SILVA FLEHR HOHBACH TEST ALBRITTON & HERBERT LLP	PCT			
4 EMBARCARDERO CENTER, SUITE 3400 SAN FRANCISCO, CA 94111-4187	NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION			
	(PCT Rule 44.1)			
AST	Date of Mailing (day/month/year) 27 MAR 2003			
Applicant's or agent's file reference FP 70224-1 balo44 - 73-1 PC	FOR FURTHER ACTION See paragraphs 1 and 4 below			
International application No. PCT/US02/09761	International filing date (day/month/year) 39 March \$002 (29.03.2002)			
Applicant RIGEL PHARMACEUTICALS, INC				
K7				
The applicant is hereby notified that the international sea Filing of amendments and statement under Article 19	arch report has been established and is transmitted herewith.			
The applicant is entitled, if he so wishes, to amend the				
When? The time limit for filing such amendments i international search report.	s normally two months from the date of transmittal of the			
Where? Directly to the International Bureau of WIP 1211 Geneva 20, Switzerland, Facsimile No	· ·			
For more detailed instructions, see the notes on the	accompanying sheet.			
2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.				
3. With regard to the protest against payment of (an) add	itional fee(s) under Rule 40.2, the applicant is notified that:			
	een transmitted to the International Bureau together with the protest and the decision thereon to the designated Offices.			
	pplicant will be notified as soon as a decision is made.			
4. Reminders				
applicant wishes to avoid or postpone publication, a notice of	nat application will be published by the International Bureau. If the withdrawal of the international application, or of the priority claim, s. I and 90 bis. 3, respectively, before the completion of the technical			
Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.				
In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.				
See the Annex to Form PC1/1B/301 and, for details about the Guide, Volume II, National Chapters and the WIPO Internet sit	e applicable time limits, Office by Office, see the PCT Applicant's e.			
Name and mailing address of the ISA/US	Authorized officer			
Commissioner for Patents Box PCT	Joseph F. Murphy Della Collins av			
Washington, D.C. 20231 Facsimile No. (703)305-3230	Telephone No. 703-308-0196			
Form PCT/ISA/220 (April 2002)	(See notes on accompanying sheet)			

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PATENT COOPERATION TREATY

· PCT

INTERNATIONAL SEARCH REPORT

ASP

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FP 70224-1 0210414-73-1					cation of Transmittal of International Search Report T/ISA/220) as well as, where applicable, item 5
International application No. PCT/US02/09761		application No. 9761 /	International filing date (day/month/year) 29 March 2002 (29.03.2002)		(Earliest) Priority Date (day/month/year) 29 March 2001 (29.03.2001)
Appl RIGE	icant EL PHA	RMACEUTICALS, INC /			
appli	cant acc	cording to Article 18. A co	py is being transmitted to the Inte	rnational	
1. J	a. V	inguage in which it was filed,	, unless otherwise indicated under t	his item.	basis of the international application in the
ł		Authority (Rule 23.1(b)).	and/or amino acid sequence discl		e international application furnished to this e international application, the international
	\boxtimes	contained in the international	l application in written form.		
		filed together with the interr	national application in computer rea	dable forn	n.
		furnished subsequently to th	is Authority in written form.		
		furnished subsequently to this Authority in computer readable form.			
		the statement that the subsectinternational application as i		isting doe	s not go beyond the disclosure in the
		the statement that the information been furnished.	nation recorded in computer readabl	e form is	identical to the written sequence listing has
2.	\boxtimes	Certain claims were found	unsearchable (See Box I).		
3.		Unity of invention is lacking	g (See Box II).		
4.	With re	gard to the title,			1
	A	the text is approved as subm			
		the text has been established	by this Authority to read as follow	rs:	
5.	5. With regard to the abstract,				
٥.	\boxtimes	the text is approved as subm	itted by the applicant.		
		= =		s Authorit	y as it appears in Box III. The applicant
l			n the date of mailing of this internal		
6. The figure of the drawings to be published with the abstract is Figure No.					
		as suggested by the applicar	nt.		None of the figures
		because the applicant failed	to suggest a figure.		
		because this figure better ch	naracterizes the invention.		

Form PCT/ISA/210 (first sheet) (July 1998)

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/09761

	Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)				
Thi	s interna	tional report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:			
1.		Claim Nos.: because they relate to subject matter not required to be searched by this Authority, namely:			
2.	\boxtimes	Claim Nos.: 1-33 (IN PART) because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically: Please See Continuation Sheet			
3.	6.4(a).	Claim Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule			
Box	II Ob	servations where unity of invention is lacking (Continuation of Item 2 of first sheet)			
This	Internat	ional Searching Authority found multiple inventions in this international application, as follows:			
1. 2. 3.		As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:			
4.	nark on 1	No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.			

Form PCT/ISA/210 (continuation of first sheet(1)) (July 1998)

$\begin{tabular}{ll} \textbf{INTERNATIONAL SEARCH REPORT} \\ \end{tabular}$

International application No.

PCT/US02/09761

TA CT A	CCIETO A TRIONI OF CUID IFOTE MATTER				
	A. CLASSIFICATION OF SUBJECT MATTER				
IPC(7)	: C12N 15/12, 15/63, 15/00; C07K 14/00; C0	7H 21/04			
US CL	: 435/69.1, 320.1, 325; 530/350; 536/23.5				
	o International Patent Classification (IPC) or to both	national classification and IPC			
B. FIEI	LDS SEARCHED				
Minimum do	ocumentation searched (classification system followe	ed by classification symbols)			
	135/69.1, 320.1, 325; 530/350; 536/23.5				
	,,,,,,				
Documentati	on searched other than minimum documentation to t	he extent that such documents are include	d in the fields searched		
		·			
F1 4		4.4. 1	•		
	ata base consulted during the international search (na	ime of data base and, where practicable, s	search terms used)		
EAST MED	LINE BIOSIS EMBASE CAPLUS				
C. DOC	UMENTS CONSIDERED TO BE RELEVANT				
Category *	Citation of document, with indication, where a	appropriate, of the relevant passages	Relevant to claim No.		
Y	US 5,494,818 A (BAKER et al.) 27 February 1996	5 (27.02.1996) see entire document.	1-33		
	·				
Y	US 5,391,490 A (VARSHAVAKY et al.) 21 Febru	ary 1995 (21.02.1995) see entire	1-33		
_	document.	,			
Y	Gong L et al. Identification of a novel isopeptidase	with dual specificity for ubiquiting and	1-33		
•	NEDD8-conjugated proteins. J Biol Chem. 12 MA		1-33		
	14212-14216, see entire document.	11 2000, Vol.275, 110.19 , pages			
	14212-14210, see endre document.	ĺ			
***	DATE OF THE STATE				
Y	BAEK SH et al. Molecular cloning of a novel ubiq		1-33		
	isopeptidase activity in chick skeletal muscle. J Bio	ol Chem. 10 October 1997 vol.272			
	no.41,pages 25560-25565, see entire document.				
Y	GONG L et al. Differential regulation of sentrinize	ed proteins by a novel sentrin-specific	1-33		
	protease. J Biol Chem. 04 February 2000, VOL.2	75, NO.5, pages 3355-3359, see entire			
	document.	, , , , , , , , , , , , , , , , , , , ,			
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Further	documents are listed in the continuation of Box C.	See patent family annex.			
<u> </u>		1 · · · · · · · · · · · · · · · · · · ·	1 632 1.4.		
5	pecial categories of cited documents:	"T" later document published after the inter date and not in conflict with the applica			
"A" document	defining the general state of the art which is not considered to be	principle or theory underlying the inver			
of particu	lar relevance				
"E" earlier an	plication or patent published on or after the international filing date	"X" document of particular relevance; the considered novel or cannot be considered.			
L carner ap	phoanon of patent phonshed of of after the international timing date	when the document is taken alone	ed to mvoive an arvenuve step		
	which may throw doubts on priority claim(s) or which is cited to		1		
	the publication date of another citation or other special reason (as	"Y" document of particular relevance; the c			
specified)	1	considered to involve an inventive step corabined with one or more other such			
"O" document	referring to an oral disclosure, use, exhibition or other means	being obvious to a person skilled in the			
	published prior to the international filing date but later than the	"&" document member of the same patent for	amily		
priority date claimed					
Date of the actual completion of the international search Date of mailing of the international search report					
		1 = a 2001 to 0.000 //	JU3"		
	27 January 2003 (27.01.2003)				
Name and m	ailing address of the ISA/US	Authorized officer			
	nmissioner of Patents and Trademarks	Joseph E. Mussley A //	1.11.		
Box PCT Washington, D.C. 20231 Joseph F. Murphy			Cellons for		
	Facsimile No. (703)305-3230 Telephone No. 703-398 0196				
1					
Form PCT/IS.	A/210 (second sheet) (July 1998)		ν		

INTERNATIONAL SEARCH REPORT	
Continuation of Box I Reason 2: Claims 1-33 are unsearchable to the extent that they require reference to the specified sequences from the set Applicant did not furnish a machine readable copy of the sequence listing, no meaningful search of the sequence out by this Authority. However, the subject matter of the claims has been searched to the extent post-balance of the description.	ences per se can be

PCT/US02/09761

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty and of the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and derivings) may be succeeded during the international preliminary examination procedure, these is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the letter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

The claims only.

The description and the drawings may only be amended during international preliminary examination under Chapter IL

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be cannidated as having been received on time if they are received by the International Buress after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to flie the omendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A sepisocement shoot must be submitted for each shoot of the claims which, on account of an amendment or amendments, differs from the shoet originally filed.

All the claims appearing on a replacement short must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confounded with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

-The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate; in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

NOTES TO FORM PCT/ISA/220 (continued)

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are \$1]:
 "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers;
 claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- (Where originally there were 15 claims and after amendment of all claims there are 11):
 "Claims 1 to 15 replaced by amended claims 1 to 11."
- 3. (Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims):
 "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of amendments are made]:
 "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claims 14; claims 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

The statement should be brief, it should not exceed 500 words if in English or if insulated into English.

It should not be confounded with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a beading, prefainbly by using the words "Statement under Article 19(1)."

It should not contain any disparaging comments on the international search report or the sulevance of citations contained in the report. Reference to citations, relevant to a given cinim, contained in the international search report may be made only in connection with an amendment of that claim.

La what language?

The amendments must be made in the language in which the international application is published. The letter and any statement accompanying the amendments must be in the same language as the international application if that language is English or French; otherwise, it must be in English or French, at the choice of the applicant.

Consequence if a demand for international preliminary examination has already been filed?

If, at the time of filing any amendments under Article 19, a dunand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase?

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.